



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0455; FRL-9364-8]

Metconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerance for residues of metconazole in or on corn, sweet, stover. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0455, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-9096; email address: gibson.tamue@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0455 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0455, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7937) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that the tolerance in the 40 CFR 180.617 be amended by increasing the established tolerance for residues of the fungicide metconazole, 5-[(4-chlorophenyl)-methyl]-2, 2-dimethyl-1-(1H-1, 2, 4-triazol-1-ylmethyl) cyclopentanol, measured as the sum of cis- and trans- isomers, in or on corn, sweet, stover from 4.5 parts per million (ppm) to 25.0 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the proposed tolerance level by increasing the tolerance for residues of corn, sweet, stover to 30 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for metconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with metconazole follows.

EPA's analysis of the impact of the proposed increase of the corn stover tolerance will have a minimal impact on exposure of livestock to metconazole and will not change the safety determination EPA made for metconazole in tolerance rulemaking published in the **Federal Register** of August 17, 2011 (76 FR 50898) (FRL-8882-7) and the initial establishment of the corn stover tolerance published in the **Federal Register** of May 7, 2009, 74 FR 21260, FRL-8408-6. In the aggregate risk assessment supporting those actions, EPA included exposure from previously established tolerances for corn and corn by-products, including corn stover (See Metconazole: Human Health Assessment for

Proposed Uses on Tuberous and Corm Vegetables Subgroup 1C and Bushberry Subgroup 13-07B, EPA Docket Number EPA-HQ-OPP-2010-0621). In that risk assessment, metconazole exposure to humans due to the presence of metconazole in animal livestock feed items was calculated based on the tolerance levels in livestock commodities consumed by humans (e.g., meat and milk). Tolerance levels in livestock commodities are driven by the tolerance levels in livestock feed items, taking into account the makeup of the livestock diet. EPA's analysis of the impact of raising the corn stover tolerance shows that there will be no increase in the maximum reasonably balanced dietary burden for beef cattle, swine, or poultry but a small increase for dairy cattle. There is no increase for beef cattle, swine, or poultry because sweet corn stover is only a significant feed item in dairy cattle. Although there is an increase in the estimated dietary burden of metconazole for dairy cattle associated with the proposed increase in the corn stover tolerance, the increase is relatively small (less than 15 percent) and, based on data from a cattle feeding study with metconazole, EPA has determined that the small increase in dietary burden to dairy cattle will not result in metconazole residues in food commodities from dairy cattle that exceed existing tolerances. Thus, despite the increase in the corn stover tolerance, the aggregate risk assessment underlying the 2009 and 2011 metconazole rulemakings, which assumed residue levels in food commodities from dairy cattle at existing tolerances levels, remains an accurate estimate of metconazole risk.

In the August 17, 2011 and May 7, 2009 **Federal Register** actions, EPA concluded that there is reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to metconazole residues. That conclusion was based on the findings that metconazole did not pose either an acute

or cancer risk and that chronic exposure to metconazole from food and water falls well below the safe exposure level for all population groups, including children 1 to 2 years old, the population group receiving the greatest exposure. Refer to the August 17, 2011 (76 FR 50898) (FRL-8882-7), **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** documents in support of this action.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate high performance liquid chromatography with tandem mass spectrometry (Method D0604, entitled “The Determination of Residues of BAS 555 F and its Metabolites in Corn and Cotton Matrices Using LC/MS/MS”), with the German multi-residue method DFG S19 as a confirmatory method, is adequate as an enforcement method. Method D0604 determines metconazole (cis – and trans –isomers), 1,2,4-triazole (T), triazolyalanine (TA), and triazolylacetic acid (TAA). DFG S19 uses gas chromatography/nitrogen phosphorus detection (GC/NPD) or gas chromatography/mass spectrometric detection (GC/MS). The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for metconazole on corn, sweet, stover.

C. Revisions to Petitioned-For Tolerances

Based on the analysis of the residue field trial data on field corn stover and using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures, the tolerance for sweet corn stover was increased.

V. Conclusion

Therefore, tolerances are established for residues of metconazole, 5-[(4-chlorophenyl)-methyl]-2, 2-dimethyl-1-(1H-1, 2, 4-triazol-1-ylmethyl) cyclopentanol, measured as the sum of cis- and trans- isomers, in or on corn, sweet, stover at 30.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not

subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In

addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 26, 2012.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.617, revise the following entry in the table in paragraph (a) to read as follows:

§ 180.617 Metconazole; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Corn, sweet, stover	30.0
* * *	* *

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[FR Doc. 2012-27191 Filed 11/06/2012 at 8:45 am; Publication Date: 11/07/2012]